

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Minoru FUJIMORI et al.

Serial No. 09/816,391

Filed March 26, 2001

THE COMMISSIONER IS AUTHORIZED
TO CHARGE ANY DEFICIENCY IN THE
FEE FOR THIS PAPER TO DEPOSIT
ACCOUNT NO. 23-0975.

Attn: **BOX MISSING PARTS**

Docket No. 2001_0206A

**ANAEROBIC BACTERIUM AS A DRUG FOR
CANCER GENE THERAPY**

SUBMISSION OF EXECUTED DECLARATION

Assistant Commissioner for Patents,
Washington, DC 20231

Sir:

Enclosed herewith is an executed Declaration for the above-identified application which was originally filed without an executed Declaration.

The Declaration identifies the application by the Title, name of the inventors, and filing date of the application.

Accordingly, it is submitted that the present application now complies with the requirements of 37 CFR 1.53(d). Enclosed herewith is the \$130.00 surcharge required by 37 CFR 1.16(e).

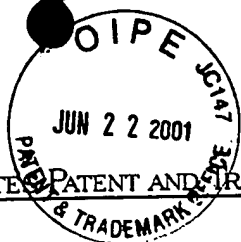
Early issuance of a filing receipt is therefore requested.

Respectfully submitted,

Minoru FUJIMORI et al.

By: Warren M. Cheek, Jr.
Warren M. Cheek, Jr.
Registration No. 33,367
Attorney for Applicants

WMC/dlk
Washington, D.C. 20006-1021
Telephone (202) 721-8200
Facsimile (202) 721-8250
May 24, 2001



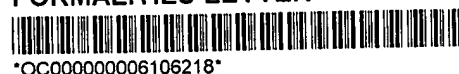
UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
09/816,391	03/26/2001	Minoru Fujimori	2001_0206A

CONFIRMATION NO. 7242

FORMALITIES LETTER



OC00000006106218

000513
WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

Date Mailed: 05/23/2001

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.
- The balance due by applicant is \$ 130.
- The paper or compact disc copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e). Applicant must provide a substitute paper or compact disc copy of the "Sequence Listing", as well as an amendment directing its entry into the application OR a substitute computer readable form (CRF) copy of the "Sequence Listing". These two items must be the same. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000).

For questions regarding compliance to these requirements, please contact:

- For Rules Interpretation, call (703) 308-4216
- To Purchase PatentIn Software, call (703) 306-2600
- For PatentIn Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov

A copy of this notice MUST be returned with the reply.



Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART.2 - COPY TO BE RETURNED WITH RESPONSE



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Minoru FUJIMORI et al.

Serial No. 09/816,391

Filed March 26, 2001

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Attn: BOX MISSING PARTS

Attorney Docket No. 2001_0206A

ANAEROBIC BACTERIUM AS A DRUG FOR
CANCER GENE THERAPY

PATENT OFFICE FEE TRANSMITTAL FORM

Assistant Commissioner for Patents,
Washington, DC 20231

Sir:

Attached hereto is a check in the amount of \$130.00 to cover Patent Office fees relating to filing the following attached papers:

Late filing of executed Declaration \$130.00

A duplicate copy of this paper is being submitted for use in the Accounting Division, Office of Finance.

The Commissioner is authorized to charge any deficiency or to credit any overpayment associated with this communication to Deposit Account No. 23-0975, with the EXCEPTION of deficiencies in fees for multiple dependent claims in new applications.

Respectfully submitted,

Minoru FUJIMORI et al.

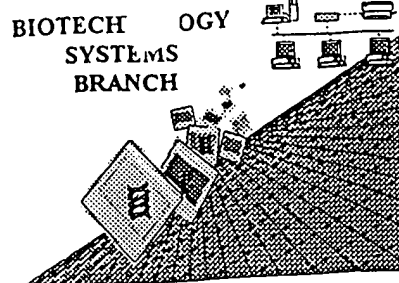
By Warren M. Cheek, Jr.
Warren M. Cheek, Jr.
Registration No. 33,367
Attorney for Applicants

WMC/dlk
WENDEROTH, LIND & PONACK, L.L.P.
2033 K St., N.W., Suite 800
Washington, D.C. 20006-1021
Telephone (202) 721-8200
May 24, 2001

[Check No. _____]
2001_0206A

O I P E
JUN 22 2001
PACIFIC
JULY 1 2001

**RAW SEQUENCE LISTING
ERROR REPORT**



The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 09/816,391
Source: O I P E
Date Processed by STIC: 4-9-01

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.

PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216.

PATENTIN 2.1 e-mail help: patin21help@uspto.gov or phone 703-306-4119 (R. Wax)

PATENTIN 3.0 e-mail help: patin3help@uspto.gov or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 3.0 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW:

Checker Version 3.0

The Checker Version 3.0 application is a state-of-the-art Windows based software program employing a logical and intuitive user-interface to check whether a sequence listing is in compliance with format and content rules. Checker Version 3.0 works for sequence listings generated for the original version of 37 CFR §§1.821 - 1.825 effective October 1, 1990 (old rules) and the revised version (new rules) effective July 1, 1998 as well as World Intellectual Property Organization (WIPO) Standard ST.25.

Checker Version 3.0 replaces the previous DOS-based version of Checker, and is Y2K-compliant. Checker allows public users to check sequence listings in Computer Readable form (CRF) before submitting them to the United States Patent and Trademark Office (USPTO). Use of Checker prior to filing the sequence listing is expected to result in fewer errored sequence listings, thus saving time and money.

Checker Version 3.0 can be down loaded from the USPTO website at the following address:

<http://www.uspto.gov/web/offices/pac/checker>

Raw Sequence Listing Error Summary

ERROR DETECTED SUGGESTED CORRECTION

SERIAL NUMBER: 09/816,391

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

- 1 ☒ **Wrapped Nucleics** The number/text at the end of each line "wrapped" down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".
- 2 ☐ **Wrapped Aminos** The amino acid number/text at the end of each line "wrapped" down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".
- 3 ☐ **Incorrect Line Length** The rules require that a line not exceed 72 characters in length. This includes spaces.
- 4 ☐ **Misaligned Amino Acid Numbering** The numbering under each 5th amino acid is misaligned. This may be caused by the use of tabs between the numbering. It is recommended to delete any tabs and use spacing between the numbers.
- 5 ☐ **Non-ASCII** This file was not saved in ASCII (DOS) text, as required by the Sequence Rules.
Please ensure your subsequent submission is saved in ASCII text so that it can be processed.
- 6 ☐ **Variable Length** Sequence(s) ____ contain n's or Xaa's which represented more than one residue.
As per the rules, each n or Xaa can only represent a single residue.
Please present the maximum number of each residue having variable length and indicate in the (ix) feature section that some may be missing.
- 7 ☐ **PatentIn ver. 2.0 "bug"** A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequence(s) _____. Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies primarily to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
- 8 ☐ **Skipped Sequences (OLD RULES)** Sequence(s) ____ missing. If intentional, please use the following format for each skipped sequence:
(2) INFORMATION FOR SEQ ID NO:X:
(i) SEQUENCE CHARACTERISTICS: (Do not insert any headings under "SEQUENCE CHARACTERISTICS")
(xi) SEQUENCE DESCRIPTION: SEQ ID NO:X:
This sequence is intentionally skipped

Please also adjust the "(iii) NUMBER OF SEQUENCES:" response to include the skipped sequence(s).
- 9 ☐ **Skipped Sequences (NEW RULES)** Sequence(s) ____ missing. If intentional, please use the following format for each skipped sequence.
<210> sequence id number
<400> sequence id number
000
- 10 ☐ **Use of n's or Xaa's (NEW RULES)** Use of n's and/or Xaa's have been detected in the Sequence Listing.
Use of <220> to <223> is MANDATORY if n's or Xaa's are present.
In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
- 11 ☐ **Use of "Artificial" (NEW RULES)** Use of "Artificial" only as "<213> Organism" response is incomplete, per 1.823(b) of New Sequence Rules.
Valid response is Artificial Sequence.
- 12 ☐ **Use of <220> Feature (NEW RULES)** Sequence(s) ____ are missing the <220> Feature and associated headings.
Use of <220> to <223> is MANDATORY if <213> ORGANISM is "Artificial Sequence" or "Unknown"
Please explain source of genetic material in <220> to <223> section.
(See "Federal Register," 6/01/98, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of new Rules)
- 13 ☐ **PatentIn ver. 2.0 "bug"** Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing).
Instead, please use "File Manager" or any other means to copy file to floppy disk.



OIEP

RAW SEQUENCE LISTING
PATENT APPLICATION: US/09/816,391

DATE: 04/09/2001
TIME: 09:43:22

Input Set : A:\sequence list.txt
Output Set: N:\CRF3\04092001\I816391.raw

3 <110> APPLICANT: KYOWA HAKKO KOGYO CO., LTD.
W--> 4 <120> TITLE OF INVENTION: Anaerobic bacterium as a drug for cancer gene therapy
W--> 5 <130> FILE REFERENCE: DK04F318(US)
W--> 6 <140> CURRENT APPLICATION NUMBER:
C--> 7 <141> CURRENT FILING DATE: 2001-03-26
8 <150> PRIOR APPLICATION NUMBER: JP 00/287688
W--> 9 <151> PRIOR FILING DATE: 2000-9-21
W--> 10 <160> NUMBER OF SEQ ID: 3

Does Not Comply
Corrected Diskette Needed
pp. 1, 2

ERRORED SEQUENCES

W--> 11 <210> SEQ ID NO: 1
12 <211> LENGTH: 600
13 <212> TYPE: DNA
14 <213> ORGANISM: Bifidobacterium longum
W--> 15 <220> FEATURE:
16 <221> NAME/KEY: CDS
17 <222> LOCATION: (193)..(471)
W--> 18 <400> SEQUENCE: 1
E--> 19 gctgggcgcg gcggccatga agtggcttga caagcataat cttgtctgat tcgtctattt
20 (60)
E--> 21 tcaatacctt cggggaata gatgtgaaaa cccttataaa acgcgggttt tcgcagaaac
22 (120)
E--> 23 atgcgctagt atcattgatg acaacatgga ctaagcaaaa gtgcttgccc cctgacccaa
24 (180)
E--> 25 gaaggatgct tt atg gca tac aac aag tct gac etc gtt tgc aag atc gcc
26 (231)
27 Met Ala Tyr Asn Lys Ser Asp Leu Val Ser Lys Ile Ala
W--> 28 1 5 10
E--> 29 cag aag tcc aac ctg acc aag gct cag gcc gag gct gct gtt aac gcc
30 (279)
31 Gln Lys Ser Asn Leu Thr Lys Ala Gln Ala Glu Ala Ala Val Asn Ala
W--> 32 15 20 25
E--> 33 ttc cag gat gtg ttc gtc gag gct atg aag tcc ggc gaa ggc ctg aag
34 (327)
35 Phe Gln Asp Val Phe Val Glu Ala Met Lys Ser Gly Glu Gly Leu Lys
W--> 37 30 35 40 45
E--> 38 ctc acc ggc ctg ttc tcc gct gag cgc gtc aag cgc ccg gct cgc acc
39 (375)
W--> 40 Leu Thr Gly (Lue) Phe Ser Ala Glu Arg Val Lys Arg Pro Ala Arg Thr
W--> 41 50 55 60
E--> 42 ggc cgc aac ccg cgc act ggc gag cag att gac att ccg gct tcc tac
43 (423)
44 Gly Arg Asn Pro Arg Thr Gly Glu Gln Ile Asp Ile Pro Ala Ser Tyr
W--> 46 65 70 75
E--> 47 ggc gtt cgt atc tcc gct ggc tcc ctg ctg aag aag gcc gtc acc gag
(471)

"Wrapped"
nucleic acid
numbers. See
#1 on Error
Summary sheet

Invalid amino acid designator

RAW SEQUENCE LISTING
PATENT APPLICATION: US/09/816,391

DATE: 04/09/2001
TIME: 09:43:22

Input Set : A:\sequence list.txt
Output Set: N:\CRF3\04092001\I816391.raw

```
48      (471)
49      Gly Val Arg Ile Ser Ala Gly Ser Leu Leu Lys Lys Ala Val Thr Glu
W--> 50      80      85      90
E--> 51      tgacettctg ctcgtagcga ttacttcgag cattactgac gacaaagacc ccgaccgaga
52      (531)
E--> 53      tggtcggggg ctttttggtg tggtgctgtg acgtgtgtgc caaccgtatt attccggact
54      (591)
E--> 55      agttcagcg
56      (600)
```

} "wrapped"
nucleic acid
numbers. see
#1 on the
Error Summary
Sheet.

VERIFICATION SUMMARY
PATENT APPLICATION: US/09/816,391

DATE: 04/09/2001
TIME: 09:43:23

Input Set : A:\sequence list.txt
Output Set: N:\CRF3\04092001\I816391.raw

L:4 M:283 W: Missing Blank Line separator, <120> field identifier
L:5 M:283 W: Missing Blank Line separator, <130> field identifier
L:6 M:283 W: Missing Blank Line separator, <140> field identifier
L:7 M:271 C: Current Filing Date differs, Replaced Current Filing Date
L:9 M:256 W: Invalid Numeric Header Field, Wrong Prior FILING DATE:YYYY-MM-DD
L:10 M:283 W: Missing Blank Line separator, <160> field identifier
L:11 M:283 W: Missing Blank Line separator, <210> field identifier
L:15 M:283 W: Missing Blank Line separator, <220> field identifier
L:18 M:283 W: Missing Blank Line separator, <400> field identifier
L:19 M:254 E: No. of Bases conflict, LENGTH:Input:0 Counted:60 SEQ:1
M:254 Repeated in SeqNo=1
L:28 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
L:32 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
L:37 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
L:40 M:334 W: (2) Invalid Amino Acid in Coding Region, NUMBER OF INVALID KEYS:1
L:41 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
L:46 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
L:50 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
L:61 M:283 W: Missing Blank Line separator, <220> field identifier
L:63 M:283 W: Missing Blank Line separator, <400> field identifier
L:69 M:283 W: Missing Blank Line separator, <220> field identifier
L:71 M:283 W: Missing Blank Line separator, <400> field identifier